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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,987	11/06/2001	David Colclough	PU3611USW	2010

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/980,987	Applicant(s) COLCLOUGH ET AL.	
	Examiner Brenda Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-8 and 10-12 are pending in the application.

This action is in response to applicants' amendment dated July 19, 2004. Claims 5, 6 and 10-12 have been amended and claim 13 has been canceled.

Response to Amendment

Applicants' arguments filed July 19, 2004 have been fully considered with the following effect:

1. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled b), c), d), e), f), g), h) and i) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled a) the applicant's amendments and remarks have been fully considered but they are not persuasive.

a) The applicants' stated that the present application adequately teaches how to make Applicants' compound, how to use it to obtain an appropriate and/or usable form of the claimed compound in the claimed formulation to treat a mammal by applying routine skills in the pharmaceutical arts. However, claims 5 and 6 generically claim the method of treating a disorder responsive to the activity of CCK-A receptors. The rejection of claims 5 and 6 was on the grounds that it is indefinite, in that it is not known which diseases are capable of being responsive to the activity of CCK-A receptors. The scope of diseases and/or disorders associated with the activity of CCK-A receptors could alter over time. The applicants' are not entitled to preempt the efforts of others.

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Claims 5 and 6 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

2. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 2 of the last office action, which is hereby **withdrawn**.

3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejection labeled paragraph 2 of the last office action, which is hereby **withdrawn**.

4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 3 of the last office action, which is hereby **withdrawn**.

5. With regards to the 35 U.S.C. § 103, obviousness rejection of claims 1-8 and 13 over SUGG et al., U.S. Patent No. 5,646,140 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants stated that the enantiomerically enriched compound of claim 1 is not render obvious by U.S. '140. The applicants also stated that U.S. '140 discloses a "large" class of 3-amino-1,5-benzodiazepines. However, U.S. '140 specifically discloses how to prepare seven compounds of which one is the applicant's compounds i.e. example 7. Example

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1 discloses the process of separating the enantiomers of the racemic compounds using chiral hplc as claimed herein.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over SUGG et al., U.S. Patent No. 5,646,140, for reasons of record and stated above.

6. With regards to the obviousness-type double patenting rejection of claims 1-8 and 13 over claims 1-4, 6-8 and 17 of U.S. Patent No. 5,646,140 of the last office action, the applicant's arguments have been fully considered but are not found persuasive for reasons stated above with respect to the 35 U.S.C. § 103 obviousness rejection.

Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-8 and 17 of U.S. Patent No. 5,646,140, for reasons of record and stated above.

7. With regards to the obviousness-type double patenting rejection of claims 4 and 13 over claims 1-4, 6-8 and 10 of U.S. Patent No. 5,780,464 of the last office action, the applicant's arguments have been fully considered but are not found persuasive for reasons stated above with respect to the 35 U.S.C. § 103 obviousness rejection.

Claim 4 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-8 and 10 of U.S. Patent No. 5,780,464, for reasons of record and stated above.

8. With regards to the obviousness-type double patenting rejection of claims 5-8 and 13 over claims 1-4 and 6-8 of U.S. Patent No. 5,910,495 of the last office action,

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the applicant's arguments have been fully considered but are not found persuasive for reasons stated above with respect to the 35 U.S.C. § 103 obviousness rejection.

Claims 5-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-8 of U.S. Patent No. 5,646,140, for reasons of record and stated above.

In view of the amendment dated July 19, 2004, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 10-12 are vague and indefinite in that it is not known what is meant by "optionally substituted" in the optionally substituted phenyl carbamate of formula (V).
- b) Claims 10-12 are vague and indefinite in that it is not known what is meant by the variable R_1 , which is not defined within the claim.
- c) Claims 11 and 12 are vague and indefinite in that it is not known what is meant by "optionally substituted" in the optionally substituted benzyl group of R_2 .

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d) Claim 12 is vague and indefinite in that it is not known what is meant by a "derivative" which implies more than what is positively recited in the definition of the diacid (VIII).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman
Primary Examiner Art Unit 1624
September 24, 2004